DETAILED ACTION

The amendment filed 2/8/08 is acknowledged. Claims 1-11, 15-19 and 21 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, 15-19 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for phosphatidyl-L-serine sodium salt having a purity of "over 95%", including 100% purity. The product is disclosed as produced by *Streptomyces hachijoense* ATCC 19769 only and is then purified.

Therefore, this material constitutes new matter and should be deleted.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that basis is found at page 8, line 4 of the Specification. However, the recitation alluded to pertains to "titer" of phosphatidylserine" and does not address the sodium salt purity. Moreover, the process in the Examples pertains to phosphatidyl choline as the raw material rather than ethanolamine which is encompassed by the product-by-process claim as written.

Therefore, this material constitutes new matter and should be deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-6 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 6 appear internally inconsistent in being directed to a sodium salt, yet the R1 moiety is hydroxyl.

Claim 21 is vague, indefinite and confusing and lacks proper antecedent basis in the recitation of preamble "phosphatidyl-L-serine" and in the subsequent recitation of "said phosphatidylcholine reactant is completely converted to phosphatidyl-L-serine", since claims 1 and 2 are directed to "phosphatidyl-L-serine sodium salt".

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-11, 15-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Sakai (U.S. Patent No. 6,117,853)

The claims are drawn to a phosphatidyl-L-serine sodium salt product having a fatty acid composition identical to that of soybean lecithin or egg lecithin having a degree of peroxidation less than 5 produced by a certain process.

Sakai discloses a phosphatidyl-L-serine composition which contains phosphatidyl-L-serine sodium salt compositions having the same structure as claimed and which is recognized to be useful as a food additive or a pharmaceutical for oral administration. See, e.g., Examples 1 and 5. Inasmuch as a sodium phosphate buffer is used, phosphatidyl-L-serine sodium salt is present at least to some extent.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the

applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants argue that the claimed phosphatidyl-L-serine sodium salt products have unprecedented purity. However, the claims are directed to a composition containing undefined amounts of this product, and thus cannot be readily distinguished over the compositions disclosed by Sakai.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of differences with the prior art. It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

Claims 1-11, 15-20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai taken with De Ferra *et al.,* Horrobin (U.S. Patent No. 5,466,841), Puricelli, Chemical Land 21 and Kurihara *et al.*(U.S. Patent No. 5,785,984).

Sakai *et al.* is discussed above. Even though the reference does not explicitly recite the sodium salt of phosphatidyl serine, it clearly recognizes that at least the sodium salts of lysophosphatidyl serine. In addition, De Ferra discloses the conversion of calcium salts to any other salt using conventional techniques, which strongly suggests that one of ordinary skill in the art recognizes that various salts of phosphatidyl serine, including sodium salts, were well known in the art at the time the claimed invention was made (See, e.g., col. 4, lines 30-33).

The reference differs from the claimed invention in that no cosmetics or pharmaceutical preparations containing phosphatides are disclosed. However, each of Horrobin (U.S. Patent No. 5,466,841), Puricelli, and Chemical Land 21 discloses pharmaceutical compositions which are pharmaceuticals useful as cosmetics and/or food additives See, e.g., Horrobin, See, e.g., col. 13, line 45 et seq. and claim 4; Puricelli, pages 3-4 and Examples; and Chemical Land 21, General Description and Applications..

In addition Kurihara *et al.* disclose edible products containing soybean lecithin (See, e.g., Examples 4-5) or phosphates,(See, e.g., Examples 21, 23, 27, 29). Kurihara *et al.* also demonstrates that various forms of providing pharmaceuticals and/or cosmetics are old and well known in the art. See, e.g., col. 7-9.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the product of Sakai, if necessary, as suggested by De Ferra *et al.* for use in cosmetics and pharmaceuticals by adding suitable carriers and providing the compositions in various forms, as suggested by the teachings of Sakai, De Ferra *et al.* and Kurihara *et al.*, for the expected benefit of providing compositions which are orally administratable and that have favorable organoleptic as well as superior pharmaceutical and cosmetic properties.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that the "high purity level of the presently claimed phosphatidyI-L-serine product is achieved by novel and non-obvious aspects of the present invention including catalyzing the enzymatic reaction which produces the claimed phosphatidyl-L-serine with phospholipase D from *S. hachijoense*, which catalyzes a complete conversion from phosphatidylcholine to phosphatidyI-L-serine". However, the claims are not directed to a phosphatidyl-L-serine product consisting of choline ($-C_3H_2-CH_2-N(CH_3)_3$) exclusively as alleged. The product-by-process claimed has not clear nexus with the example 2 cited.

In addition, the composition claims are directed to a composition containing undefined amounts of this product, and thus cannot be readily distinguished over the compositions disclosed by Sakai. Therefore, applicant's arguments directed to differences in purity are not relevant to the claimed invention.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
Art Unit 1651